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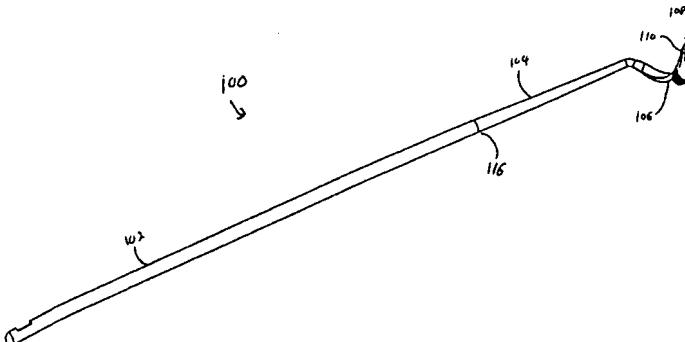
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(54) Title: METHOD AND APPARATUS FOR SUTURING



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(57) **Abstract:** The present invention provides new and useful devices and techniques for use in suturing. These devices and techniques are particularly useful in laparoscopic, arthroscopic, and/or open surgical procedures. A method according to the present invention is characterized by releasably coupling a suture to a suture device, causing the tip of the suture device and a portion of the suture to penetrate a tissue, and releasing the suture from the suture device, so the suture may be drawn through the tissue for completion of a suturing procedure. One type of suturing device according to the invention is characterized by a handle with an elongated shaft with a sharpened tip configured to hold a suture at a selected point on the suture. Another type of device according to the principles of the invention is characterized by new and useful structures and techniques for loading the suture into the device. According to still another aspect of the present invention, different shaped suture tips are provided for the selection of the most effective tip shape for a given application. A suturing device according to the present invention may also be configured for use with a needle point swaged to a suture. Yet another type of suturing device according to the principles of present invention includes a tissue support structure disposed adjacent the sharpened tip, which may move relative to the sharpened tip to facilitate penetration of the tip through a tissue.

## METHOD AND APPARATUS FOR SUTURING

### RELATED APPLICATION/CLAIM OF PRIORITY

This Application is related to and claims priority from Provisional Application Serial Number 60/129,993 entitled "Suture Leader for Shuttleless suturing", filed April 19, 1999.

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### FIELD OF INVENTION

The present invention relates to methods and apparatus for use in surgical suturing.

### BACKGROUND OF INVENTION

Suture is often used bring two pieces of tissue together and hold the tissues as 10 they heal. Needles allow a surgeon to pierce tissue and pull suture through that tissue. In many procedures, there is adequate space in the wound or incision to manipulate needles and needle holding instruments. The move by surgeons toward less invasive and minimally invasive surgeries has created the need for instruments to be designed to function in limited space and with longer reaches. Standard surgical instruments are 15 being stretched and downsized to pass through tunnels in the tissue called cannulas or portals measuring as small as 5 millimeters in diameter and in a variety of lengths. There is a need for improved surgical instruments to manipulate and control sutures during surgical operations.

## SUMMARY OF THE INVENTION

The present invention provides new and useful devices and techniques for use in suturing. These devices and techniques are particularly useful in laparoscopic, arthroscopic, and/or open surgical procedures.

5        One type of suturing device according to the invention is characterized by a handle with an elongated shaft with a sharpened tip configured to hold a suture at a selected point on the suture. Several different types of structures for holding the suture to the sharp tip are provided according to the principles of the invention. For example, one such structure comprises a tapered opening formed in the tip, and configured to enable a suture to be wedged and held in the opening. In another example, an elongated opening is provided, which may be curved, for holding the suture. In yet another example, a locking mechanism is provided, which has a locked position for holding the suture, an unlocked position for releasing the suture, and a partially locked position for controlled adjustment of the suture position relative to the tip.

10      Another type of device according to the principles of the invention is characterized by new and useful structures and techniques for loading the suture into the device. In one example of this aspect of the present invention, a suture may be side-loaded into the device. This provides numerous advantages, including eliminating the need to thread the suture, and allowing side-release of the suture.

15      According to still another aspect of the present invention, different shaped suture tips are provided for the selection of the most effective tip shape for a given application. In one example of this aspect of the present invention, each tip may be detached from the suturing device and replaced by another tip. In another example of this aspect of the present invention, the position of each tip is adjustable relative to the shaft of the

20      suturing device for further refinement of the suturing device for a given application.

25     

A suturing device according to the present invention may also be configured for use with a needle point swedged to a suture.

Yet another type of suturing device according to the principles of present invention includes a tissue support structure disposed adjacent the sharpened tip, which may move relative to the sharpened tip to facilitate penetration of the tip through a tissue. In one example of this aspect of the present invention, a suture is carried 5 through the tissue by the tip as the tip penetrates the tissue. In another example of this aspect of the present invention, the tip engages the suture after penetration of the tissue, and draws the suture through the tissue as the tip is withdrawn from the tissue.

A method according to the present invention is characterized by releasably coupling a suture to a suture device, causing the tip of the suture device and a portion 10 of the suture to penetrate a tissue, and releasing the suture from the suture device, so the suture may be drawn through the tissue for completion of a suturing procedure.

These and other features and techniques of the present invention will become further apparent from the following detailed description and the accompanying drawings.

#### 15 BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the following illustrative Figures, which may not be to scale. In the following Figures, like reference numbers refer to similar elements throughout the Figures.

20 FIG. 1 is a perspective view of a suturing device in accordance with the present invention;

FIG. 2 is a close-up perspective view of the sharpened tip at the distal end of the suturing device of FIG. 1;

25 FIGS. 3-5 illustrate the relative positions of a suture and a suturing device during coupling of a suture with the suturing device in accordance with the principles of the present invention;

FIGS. 6A-6B schematically illustrate the manner in which a suture is trapped and held by an opening in the sharpened tip of a suturing device in accordance with the principles of the present invention;

5 FIGS. 7-10 illustrate successive steps in applying a suture to tissue using a suturing device in accordance with the principles of the present invention;

FIGS. 11-17 schematically illustrate sharpened tips and different configurations for an opening for use in coupling a suture with the sharpened tip in accordance with the principles of the present invention;

10 FIG 18-21 schematically illustrate a suturing device with a locking mechanism according to the principles of the present invention;

FIG. 22 schematically illustrates a sharpened tip with a combination of openings for use in coupling a suture with the sharpened tip in accordance with the principles of the present inventions;

15 FIGS. 23-29 schematically illustrate different configurations for a sharpened tip with an opening for coupling a suture with the sharpened tip in accordance with the principles of the present invention;

FIGS. 30-32 schematically illustrate different ways for coupling a needle with a swaged suture to a suturing device in accordance with the principles of the present invention;

20 FIG. 33 schematically illustrates another way for coupling a suture to a suturing device in accordance with the principles of the present invention; and

FIG. 34-36 illustrate a suture device in which a tissue support device is provided in accordance with the principles of the present invention.

## DETAILED DESCRIPTION

As set forth above, the present invention provides several types of devices and techniques which are useful in suturing, for example in connection with laparoscopic, arthroscopic, and/or open surgical procedures. Examples of devices and techniques 5 according to the principles of the present invention are described below in connection with particular embodiments, but it will be clear to those skilled in the art that aspects of the present invention found in one example may be practiced alone or in combination with (or even in lieu of) devices and techniques of the other examples.

One type of suturing device in accordance with the present invention is shown in 10 FIG. 1. Suturing device 100 has a handle 102, a shaft 104 connected to the handle, and a tip 106 connected to the other (distal) end of the shaft. Typically, the handle 102 may be 4 to 6 inches long, and the shaft 104 may typically be from 1 to 24 inches, depending on the application. The shaft is typically 2 to 3 millimeters in diameter and formed of a rigid substance. Tip 106 includes a sharpened point 108 and an eyelet (or 15 opening) 110.

FIG. 2 shows a close-up view of tip 106. Tip 106 has a curved, hook-like shape for convenient delivery of a suture, as discussed further below. Eyelet 110 has a top portion 112 configured to be wider than a suture used in connection with the suturing device, and a narrowed bottom portion 114 for trapping the suture.

20 Referring now to FIGS. 3 through 6B, a method according to the present invention is shown. Suture 302 is threaded through eyelet 110 as shown in FIG. 3 and 4 until a selected length of suture (labeled "d") is extended through suturing device 100 as shown in FIG. 4. Preferably, length d is about 2 inches. Once the selected point of 25 suture is in eyelet 110, length d is drawn downward, as shown in FIG. 5, trapping the suture in eyelet 110. FIG 6A shows the position of the suture in the wider top portion 112 of eyelet 110 prior to the drawing downward step. 6B shows the suture wedged into the narrowed bottom portion 114 of eyelet 110 after the downward drawing step of

FIG. 5. The suture in FIG. 6B is thus trapped in the narrowed bottom portion 114 in accordance with one aspect of the invention.

FIGS. 7 through 10 show the use of the above described embodiment of the present invention in the repair of a gap 702 formed in tissue 704. As shown in FIGS. 7 and 8, suturing device 100 with suture 302 is partially inserted into a portion of tissue 704. Sharpened tip 106 of suturing device 100 penetrates tissue 704, thereby delivering suture 302 to the other side of tissue 704. A second tool 902 (FIG 9) is used to assist in the release of suture 302 from eyelet 110, and to draw the short end of suture 302 the rest of the way through tissue 704 and fully disengage suture 302 from device 100 (See FIG. 10). Exhibit A shows color illustrations similar to FIGS. 7 through 10 and which may more clearly illustrate the contrast between the tool, the suture, and the tissue that is being sutured.

FIG 11 shows a close-up of a tapered eyelet 110 of the type described in FIGS. 1 through 10, and further illustrating the orientation of the tapered eyelet 110 relative to the sharpened tip 106.

FIG 12 shows a close-up of a sharpened tip 1202 with an alternative embodiment of an eyelet 1204 in accordance with the principles of the present invention. Eyelet 1202 has a tapered central portion 1206 which may trap a suture from either the top wider portion 1208 or the bottom wider portion 1210 of eyelet 1204. One advantage of this embodiment is that the device operator may disengage suture 302 from device 100 either by pulling the suture towards the wider top portion 1208 or the wider bottom portion 1210. It will be clear to one skilled in the art that this embodiment of the present invention provides added flexibility in the manner in which the suture can be released.

FIG. 13 shows a close-up of a sharpened tip 1302 with another alternative embodiment of an eyelet 1304 in accordance with the principles of the present invention. Eyelet 1304 is configured for side-loading of the suture into the eyelet. Eyelet 1304 is advantageous where the end of a suture is frayed, or it is otherwise difficult or time-consuming to pass lengthwise through an eyelet (as shown in FIGS. 3

and 4). The eyelet configuration shown in FIG. 13 allows for very easy loading, sliding, and release of the suture from the suturing device.

FIG. 14 shows another sharpened tip 1402 with still another embodiment of an eyelet 1404 with the feature of side-loading of a suture according to the principles of the 5 present invention. The T-shaped configuration of eyelet 1404 substantially traps the suture in eyelet 1404 while allowing the suture to slide lengthwise through the eyelet.

FIG. 15 shows yet another sharpened tip 1502 with another configuration of an eyelet 1504 with side-loading capability according to the principles of the present invention. Eyelet 1504 is configured with a deep diagonal slot 1506 which substantially 10 traps the suture while allowing the suture to slide lengthwise through the eyelet.

FIG. 16 shows yet another sharpened tip 1602 with another embodiment of an eyelet 1604 with side-loading capability according to the principles of the present invention. In FIG. 16, eyelet 1604 has a tapered configuration so that a suture may be 15 side-loaded into a suturing device and then wedged into the tapered portion of the eyelet for improved trapping of the suture.

FIG. 17 shows yet another sharpened tip 1702 with another embodiment of an eyelet 1704 with a side-loading capability according to the principles of the present invention. In Fig. 17, eyelet 1704 has an elongated and curved configuration for substantially trapping a suture while allowing the suture to slide lengthwise through the 20 eyelet. The elongated and curved configuration of the eyelet makes it very unlikely that a suture will be unintentionally released from the suturing device.

Figures 18 through 21 illustrate a suturing device with a locking mechanism for trapping a suture in an opening in a sharpened tip in accordance with the principles of present invention. As shown in FIG. 18, suturing device 1800 has a handle 1802 with 25 locking mechanism button 1804, shaft 1806, and sharpened tip 1808.

FIG 19 illustrates a close-up of sharpened tip 1808, having opening 1902 and locking element 1904. Locking element 1904 is controlled by the device operator with

button 1804 (FIG. 18). Locking element 1804 may be selectively placed in (1) an open position for inserting a suture into an opening in the sharpened tip and for release of the suture from the opening in the sharpened tip; (2) at least one partially closed position for capturing the suture and for controlled adjustment of the suture relative to the tip; and

5 (3) a locked position for trapping a suture in the opening in the sharpened tip at a selected point.

FIG. 20 further illustrates the use of the locking mechanism in accordance with the principles of the invention. FIG. 20 shows a schematic view of the sharpened tip 1808 with opening 1902. Sharpened tip 1808 has side-loading capability and locking element 1904, which can be selectively placed in any of the foregoing positions by movement of the locking element in the direction of arrow 2002. When a suture is first side-loaded, locking element 1904 is in the open position as shown in FIG. 20. As locking element 1904 is pushed forward and the side-opening 2004 is blocked-off, the suture is captured in the tip, but is not yet trapped in a particular position. In this state,

10 the suture may slide lengthwise relative to sharpened tip 1808, but may not be removed from sharpened tip 1808 unless the full length of the suture is drawn through opening 1902. As element 1904 is moved further forward, it engages the suture with a ~~light amount of friction, giving the device operator the ability to control the lengthwise movement of the suture without damaging the suture. Finally as locking element 1904~~

15 is pushed fully forward, the suture becomes wedged in opening 1902, and fixed in a locked position. Release of the suture is achieved by moving the locking button to move the locking element away from the locked position.

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In the embodiment of the present invention shown in FIG. 21, the locking element moves in the same manner as in FIG. 20, and the same locking principles apply, but no side-loading capability is provided.

Referring to FIG. 22, various combinations of eyelets may be formed on a sharpened tip in accordance with the principles of the present invention. For example, a round eyelet 2202 may be formed in addition to a deep diagonal slot 2204 on a device

tip to allow selection of fully enclosing a suture (round eyelet) or side-loading of a suture with substantial trapping of the suture (deep diagonal slot) on the same tool. As another example, the eyelet with a tapered central portion as shown in FIG. 12 may also be combined with a side-loading feature. These and other combinations in accordance with the principles of the invention are intended to be included within the scope of the present invention.

Figures 23 through 29 show different sharpened tips for use in different applications of the present invention. The sharpened tip 2302 illustrated in FIG. 23 extends substantially straight and forward from the distal end of the device shaft.

Alternatively, as shown in FIG. 24, a the sharpened tip 2402 may be angularly bent relative to the shaft in a selected direction, and angled to a side. As illustrated in FIG. 25, and sharpened tip 2502 may be further bent so that the distal portion of the tip generally points towards the proximal end of the shaft.

Referring now to FIG. 26, an alternative embodiment according the present invention is shown wherein a sharpened tip 2602 is curved at least partially about the distal end of the shaft.

in a further embodiment according to FIG. 27, a sharpened tip 2702 is formed with at least one spiral loop at the distal end of the shaft. In the illustrated example, the spiral shaped tip 2702 has about 1.5 loops. According to this embodiment of the present invention, with a suture held near the front of the spiral (see location of eyelet 2704), the suture may be passed through a tissue two or more times prior to releasing the stitch from a suturing device.

As shown in FIG. 28, a sharpened tip 28 may be configured to extend directly to one side of the distal end of the shaft.

Further, as shown in FIG. 29, a sharpened tip 2902 may be configured to extend at least partially forward from the distal end of the shaft with a concave configuration.

Each of the above sharpened tip configurations may be selected for a particular application to allow a surgeon to pierce tissue in precisely the position chosen for the optimal re-approximation of tissue. Further, each of the above sharpened tip configurations may be combined with the other various aspects of the present invention

5 to provide a wide selection of combinations to best pass suture through a substrate. For example, each of the above sharpened tip configurations may be combined with any of the eyelet configurations. Moreover, any of the eyelets could have side-loading capability and/or a locking mechanism.

In accordance with a further principle of the present invention, each tip may be 10 configured for adjustability relative to the axis of the suturing device shaft, for providing further flexibility as to the orientation in which the suture may be applied to a gap in tissue. For example, the angle of the tip in FIG. 24 relative to the shaft may be adjusted at point in the direction of arrow 2404. Similarly, the looped tip in FIG. 27 may be rotated in the direction of arrow 2706. Each of the sharpened tips disclosed thus may 15 be pivoted, rotated, or otherwise further adapted for improved application of the sharpened tip and the suture.

In accordance with a further principle of the present invention, various tips may be removed from the suturing device and replaced with an alternative tip or with a new, sharper tip. For example, referring to FIG. 24, the tip may be removed at point 2406 20 and replaced with the tip as shown in FIG. 25. Alternatively, the tip may be detached at other positions on the suturing device, such as by removing the shaft at point 116 (FIG. 1), and replacing it with a shaft carrying a differently shaped tip.

Referring now to FIGS. 30 through 32, further embodiments of the present invention configured for use with a needle point swaged to a suture are shown. As 25 shown in FIG. 30, suture 3002 with needle tip 3004 may be side-loaded into a suturing device with a shaft 3006 with a curved distal end portion 3008. In accordance with this aspect of the invention, needle tip 3004 is sharpened and acts to penetrate and lead suture 3002 through a tissue. Once the tissue is punctured, the needle tip is grasped

with a suture grasper (e.g. similar to second tool 902 in FIG. 9) and removed from the shaft in the direction of arrow 3010. The shaft is withdrawn and the suture is pulled through the tissue to complete the stitch. This embodiment also allows the simple replacement of sharp needles for tips that may have become dull. Further, tissue  
5 abrasion associated with pulling the short end of a suture through an opening already containing a length of suture is eliminated.

The shaft as in FIG. 30 may be modified as a cannula with the suture passing through a partial length of the device (FIG. 31) or the full length of the device (FIG. 32). These structures are advantageous in reducing or eliminating the amount of loose  
10 suture from the procedure area. Each of the devices in FIGS. 30 through 32 will preferably have a configuration for firmly holding the needle tip while it is piercing the tissue.

Referring to FIG. 33, alternatively, a suturing device 3300 may have a sharpened tip 3302, as in FIGS. 1 through 29, and be configured as a cannula with the suture  
15 passing through the full length of the device with a section 3304 protruding from the tip, in position for grasping as soon as the sharpened tip pierces a substrate. Section 3304 is located behind the first portion of the tip sharpened tip that pierces a tissue, so that the outwardly extending portion is carried through the tissue which has been pierced by the sharpened tip.

20 Referring now to FIG. 34, another embodiment of the invention including a tissue support structure 3402 disposed adjacent sharpened tip 3404 is shown (Exhibit B is a color illustration similar to FIG. 34, but also showing a suture). Tissue support structure 3402 is located on rotatable sheath 3406, which encases a shaft (shaft is not shown but is attached to handle 3408 and tip 3404). Rotatable sheath 3406 is preferably rotated  
25 by turning serrated handle 3410. Referring briefly to FIG. 35, a close-up view of the distal tip of a suturing device according to the principles of FIG. 34 is shown.

On occasion, the tissue to be sutured is difficult to pierce and requires pressure from behind to "push" the tissue against the sharpened tip. Use of tissue support

structure 3402 is accomplished by positioning a portion of tissue to be sutured in between sharpened tip 3404 and tissue support structure 3402. The sharpened tip is rotated through the tissue while the tissue support rotates in an opposite direction, forcing the tissue against and to be pierced by the sharpened tip. The relative rotational motion between tissue support structure 3402 and sharpened tip 3404 provides the device operator with tactile feedback as to the amount of force being applied to a tissue.

In accordance with the principles of the present invention, tissue support structure 3402 and sharpened tip 3404 are suitably configured to approach and engage a portion of tissue from a broad range of angles or positions. Combination of the various sharpened tip configurations in accordance with the present invention and the adjustability of those tips with the tissue support structure provides an even broader range of options for engaging a tissue between a sharpened tip and tissue support structure 3402.

With continue reference to FIG. 35, a suture 302 is connected with the sharpened tip and passed through the tissue as the sharpened tip pierces the tissue. After piercing, the suture is grasped on the other side of the tissue, as described above, released from the sharpened tip, and then pulled through the tissue for further use in suturing.

Referring now to FIG. 36, an alternative configuration for drawing a suture through a tissue is disclosed (Exhibit C-is-a color illustration of the elements of Figure 36). A suture 302 is connected with a sling 3602 in a tissue support device 3604. The sharpened tip pierces the tissue with the assistance of the tissue support device, and engages the suture as the sharpened tip is drawn back through the tissue and the suturing device is rotated open. In this way, if a suture is preferably applied from a side of a tissue inaccessible to the sharpened tip, the sharpened tip may be engaged from the opposite (and accessible) side of the tissue, and then made to draw the suture back through the tissue.

The present invention has been described above with reference to preferred embodiments. However, those skilled in the art having read this disclosure will recognize that changes and modifications may be made to the preferred embodiment without departing from the scope of the present invention. For example, the

5 combination of the various opening configurations with the configurations of the sharpened tip is clearly contemplated by this disclosure. Similarly, the use of the various eyelets, tip configurations, and locking mechanisms with the different tissue support features is intended. These and other changes or modifications are intended to be included within the scope of the present invention, as expressed in the following  
10 claims.

## CLAIMS

1. A suturing device comprising:
  2. a handle;
  3. an elongated shaft attached to said handle; and
  4. a sharpened tip on said elongated shaft, said sharpened tip configured to
  5. trap a suture at a selected point.
2. A suturing device as defined in claim 1, wherein said sharpened tip includes an opening configured to trap a suture at a selected point.
3. A suturing device as defined in claim 2, wherein at least a portion of the opening is dimensioned to wedge and hold a suture in the selected position
4. A suturing device as defined in claim 3, wherein said opening comprises a central portion which has said tapered configuration.
5. A suturing device as defined in claim 2, wherein said opening comprises a tapered opening.
6. A suturing device as defined in claim 2, wherein said opening comprises an elongated opening.
7. A suturing device as defined in claim 6, wherein at least a portion of said elongated opening is curved.
8. A suturing device as defined in claim 1, wherein said sharpened tip includes an opening; and
  9. a locking mechanism having at least a locked position and an unlocked position, said locking mechanism when in said locked position being configured to trap a suture in said opening.
9. A suturing device as defined in any of claims 2-8, wherein the suture comprises a length of material, and wherein said opening is configured to allow the suture to pass lengthwise through said opening.
10. A suturing device as defined in claim 9, wherein said opening is further configured to allow the suture to be side-loaded into said opening.

11. A suturing device as defined in claim 1, wherein said sharpened tip includes an opening into which a suture can be inserted, and wherein said opening is configured to allow the suture to be side loaded into said opening.

12. A suturing device as defined in claim 1, wherein said sharpened tip has a hooked configuration.

13. A suturing device as defined in claim 1, wherein said sharpened tip is angularly bent relative to said shaft in a selected direction.

14. A suturing device as defined in claim 1, wherein said sharpened tip is configured with at least one spiral loop at the distal end of the shaft.

15. A suturing device as defined in claim 1, wherein said sharpened tip is bent so the distal tip generally points towards the proximal end of the shaft.

16. A suturing device as defined in claim 1, wherein said sharpened tip is curved at least partially about the distal end of the shaft.

17. A suturing device as defined in claim 1, wherein said sharpened tip extends at an angle and to one side of the distal end.

18. A suturing device as defined in claim 1, wherein said sharpened tip extends at least partially forward from the distal end with a concave configuration.

19. A suturing device as defined in claim 1, wherein said sharpened tip extends substantially straight and forward from said distal end.

20. A suturing device as defined in claim 1, wherein said sharpened tip is selectively moveable relative to said shaft.

21. A suturing device as defined in claim 1, wherein said sharpened tip is selectively detachable from said shaft.

- 1 22. A suturing device comprising:
  - 2 a handle;
  - 3 an elongated shaft attached to said handle at a proximal end of said shaft;
  - 4 and
  - 5 a detachable needle at a distal end of said elongated shaft, said needle
  - 6 having a suture attached thereto.

23. A suturing device as defined in claim 22, wherein said distal end has a hooked configuration.

24. A suturing device as defined in claim 22, wherein said distal end is angularly bent relative to said shaft in a selected direction.

25. A suturing device as defined in claim 22, wherein said distal end is configured with at least one spiral loop at the distal end of the shaft.

26. A suturing device as defined in claim 22, wherein said distal end is bent so the distal tip generally points towards the proximal end of the shaft.

27. A suturing device as defined in claim 22, wherein said distal end is curved at least partially about the distal end of the shaft.

28. A suturing device as defined in claim 22, wherein said distal end extends at an angle and to one side of the distal end.

29. A suturing device as defined in claim 22, wherein said distal end extends at least partially forward from the distal end with a concave configuration.

30. A suturing device as defined in claim 22, wherein said distal end extends substantially straight and forward from said distal end.

31. A suturing device as defined in claim 22, wherein said needle and suture are detachably affixed to said suturing device by threading the suture through a portion of said suturing device.

32. A suturing device as defined in claim 22, wherein said needle and suture are detachably affixed to said suturing device by threading the suture through at least the distal end and the shaft of said suturing device.

33. A suturing device as defined in claim 22, wherein said needle and suture are side-loaded into said suturing device.

1        34. A suturing device comprising:  
2            a handle;  
3            an elongated shaft attached to said handle at a proximal end of said shaft;  
4            a sharpened tip at a distal end of said elongated shaft; and

5                   a tissue support device disposed adjacent said sharpened tip, configured  
6    to move relative to said sharpened tip to facilitate penetration of said sharpened tip  
7    through a tissue.

35.    A suturing device as defined in claim 34, wherein a suture is connected  
with said sharpened tip and moves with the sharpened tip as the sharpened tip  
penetrates through the tissue.

36.    A suturing device as defined in claim 34, wherein a suture is connected  
with said tissue support device, and is located to be engaged by said sharpened tip as  
said sharpened tip is withdrawn from the tissue.

1       37.    A method of delivering a suture comprising:  
2                   providing a suture device;  
3                   releasably coupling a suture with the distal end of said suture device;  
4                   penetrating a substrate with the distal end of said suture device such that  
5    said suture is partially passed through the substrate; and  
6                   releasing the suture from said suture device.

38.    A method as defined in claim 37, wherein said step of releasably coupling  
a suture with the distal end of said suture device comprises releasably trapping the  
suture in an opening at the distal end of said suture device.

39.    A method as defined in claim 37, wherein the opening is configured to trap  
and hold a suture, and said step of releasably coupling comprises releasably trapping  
and holding the suture in the opening.

40.    A method as defined in claim 37, wherein a locking mechanism associated  
with the opening has a locked position in which it releasably traps the suture in the  
opening, at least a portion of the suture being disposed in the opening, and said step of  
releasably coupling comprises placing said locking mechanism in its locked position.

41.    A method as defined in any of claims 38 through 40, wherein said step of  
releasably coupling comprises the step of side-loading the suture into the opening.

42.    A method as defined in claim 37, wherein the distal end of said suture  
device is selectively adjustable relative to the suture device.

43. A method as defined in claim 37, wherein the distal end of said suture device is selectively detachable from the suture device.

44. A method as defined in claim 43, wherein a differently shaped distal end may be attached to the distal end of said suture device.

45. A method as defined in claim 37, wherein a detachable needle is disposed at the distal end of the suture device, said needle having a suture attached thereto, and wherein said step of penetrating a substrate with the distal end of the suture comprises penetrating the substrate with said detachable needle.

46. A method as defined in claim 37, wherein a second penetrating step is performed through said substrate with said distal end of said suture device prior to said releasing step.

1       47. A method as defined in claim 37, wherein the distal end comprises a  
2       sharpened tip, a tissue support device is disposed adjacent the sharpened tip, and said  
3       step of penetrating a substrate comprises locating the tissue support device adjacent a  
4       selected portion of tissue and moving the sharpened tip relative to the tissue support  
5       device to facilitate penetration of the sharpened tip through the selected portion of  
6       tissue.

48. A method as defined in claim 47, wherein a suture is connected with the  
sharpened tip and moves with the sharpened tip as the sharpened tip penetrates  
through the tissue.

1       49. A method of delivering a suture comprising:  
2               providing a suturing device having a sharpened tip configured to penetrate  
3       a tissue, a tissue support device disposed to be located adjacent a selected portion of  
4       tissue, and being moveable relative to the sharpened tip to facilitate penetration of the  
5       sharpened tip through the selected portion of tissue and to enable the sharpened tip to  
6       be withdrawn from the selected portion of tissue;

7               providing a suture disposed to be engaged by the sharpened tip as the  
8       sharpened tip is being withdrawn from the selected portion of tissue;  
9               locating the tissue support device adjacent a selected portion of tissue and  
10       moving the sharpened tip relative to the tissue support device to pierce the selected

11 portion of tissue, and engaging the suture with the sharpened tip as the sharpened tip is  
12 withdrawn from the selected portion of tissue; and

13                   releasing the suture from the sharpened tip after the sharpened tip has  
14 been withdrawn from the selected portion of tissue.

1       50. A method as defined in claim 49, wherein the step of moving the  
2 sharpened tip relative to the tissue support device comprises rotating the tissue support  
3 device and the sharpened tip relative to each other so that the sharpened tip rotates  
4 towards the tissue support device as the sharpened tip pierces the tissue and rotates  
5 away from the tissue support device as the sharpened tip is withdrawn from the  
6 selected portion of tissue, and engaging the suture with the sharpened tip and drawing  
7 the suture through the selected portion of tissue as the sharpened tip rotates away from  
8 the tissue support device and is withdrawn from the selected portion of tissue.

1       51. A suturing device comprising:  
2                   a handle;  
3                   an elongated shaft attached to said handle;  
4                   a sharpened tip on said elongated shaft,  
5                   said sharpened tip being configured to engage a suture; and  
6                   a locking mechanism having at least a locked position and an unlocked  
7                   position, ~~said locking mechanism when in said locked position being configured to hold~~  
8                   the suture in a selected position.

52. A suturing device as defined in claim 51, wherein said locking mechanism  
has at least one partially closed position for capturing the suture and for controlled  
adjustment of the suture relative to the sharpened tip.

1       53. A suturing device comprising:  
2                   a handle;  
3                   an elongated shaft attached to said handle;  
4                   a sharpened tip on said elongated shaft,  
5                   said sharpened tip having an opening configured to allow the suture to be  
6                   side-loaded onto said device.

54. A suturing device as defined in claim 53, wherein said opening comprises a tapered opening.

55. A suturing device comprising:

a handle;

an elongated shaft attached to said handle;

a sharpened tip on said elongated shaft,

said sharpened tip having a piercing portion configured to pierce tissue during a suturing procedure; and

a suture coupled with said sharpened tip, said suture having a suture portion extending outward from said sharpened tip to permit said suture to be grasped and manipulated relative to said sharpened tip, said suture portion disposed to be carried by the sharpened tip through tissue which has been pierced by said piercing portion.

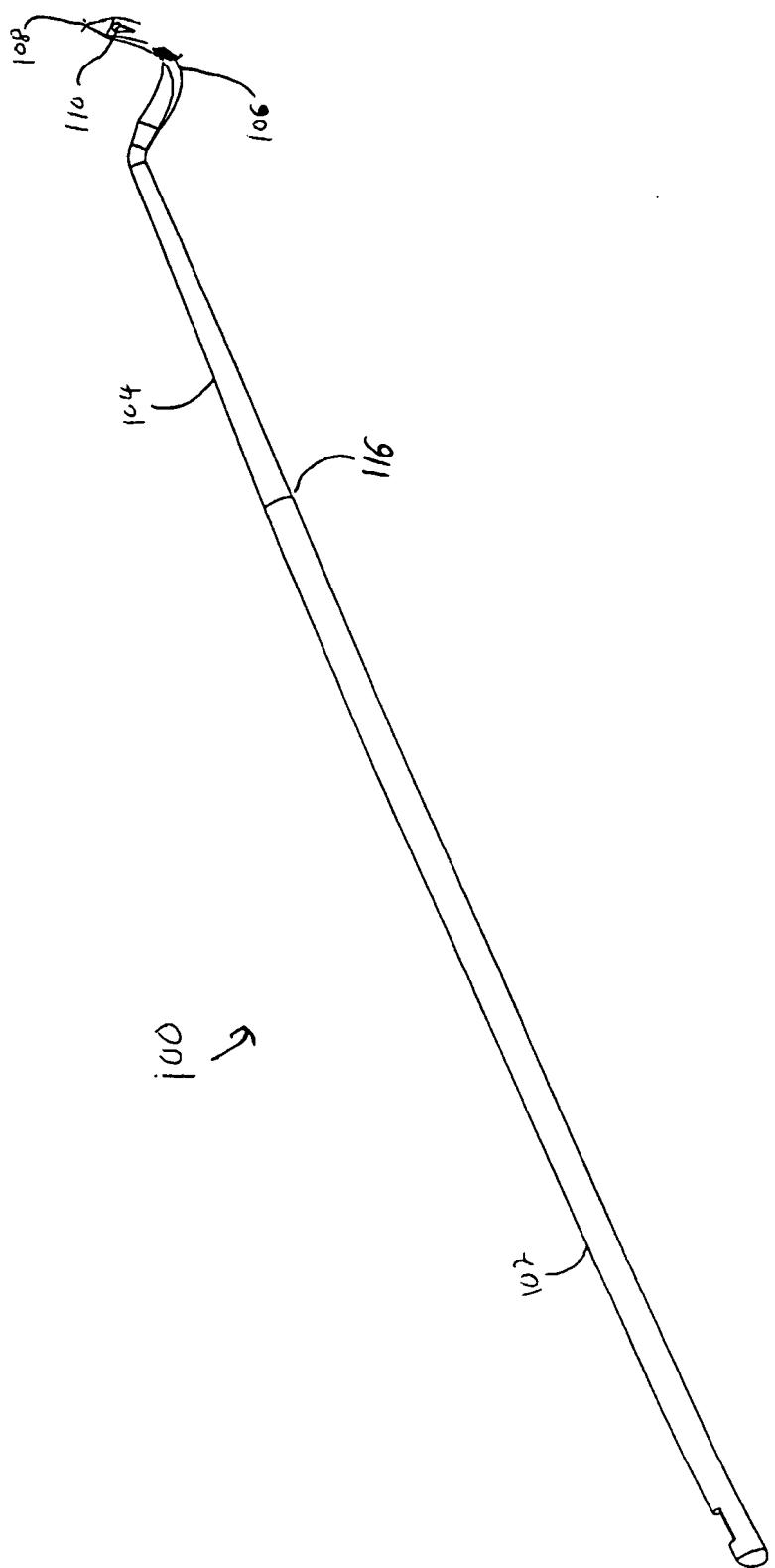


Fig. 1

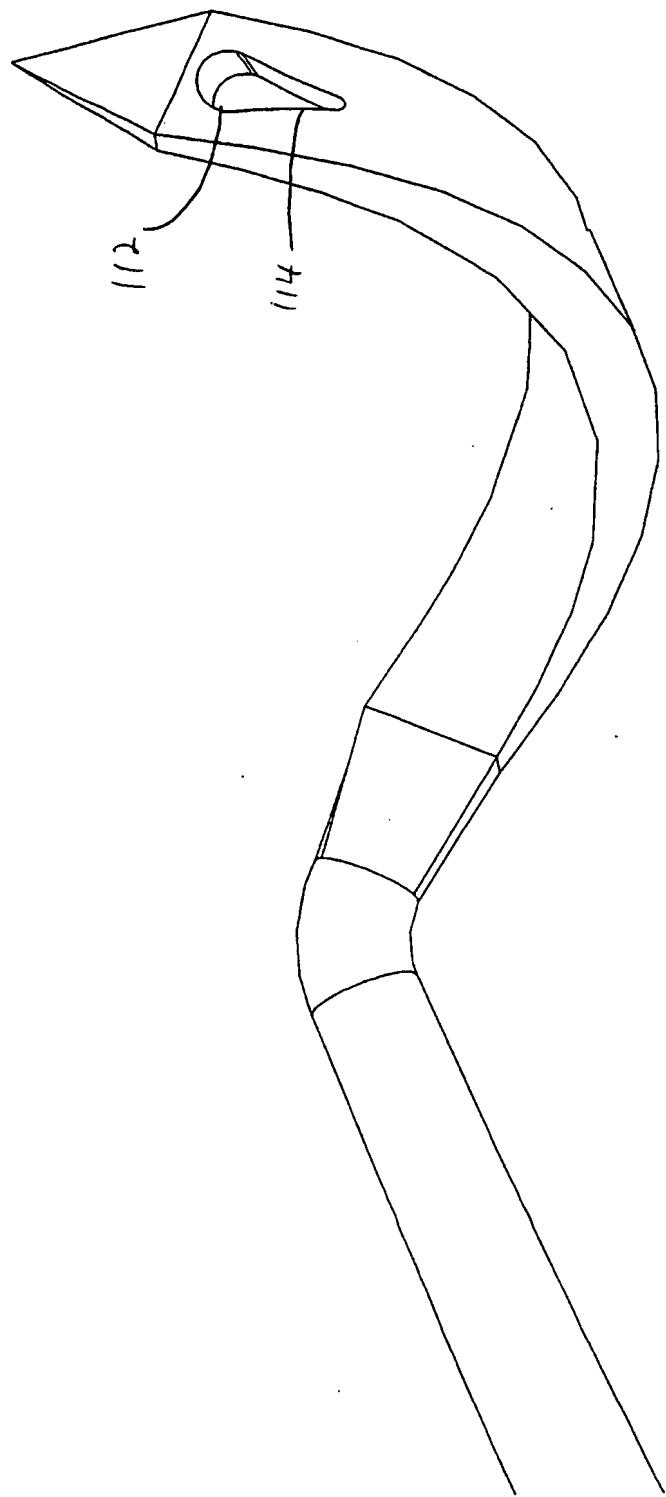


Fig. 1

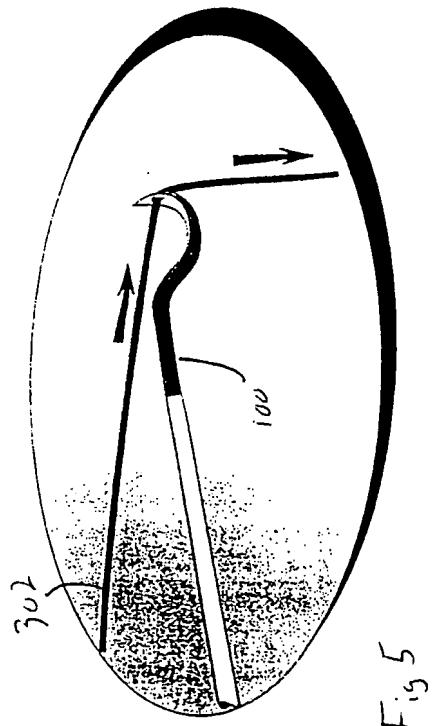
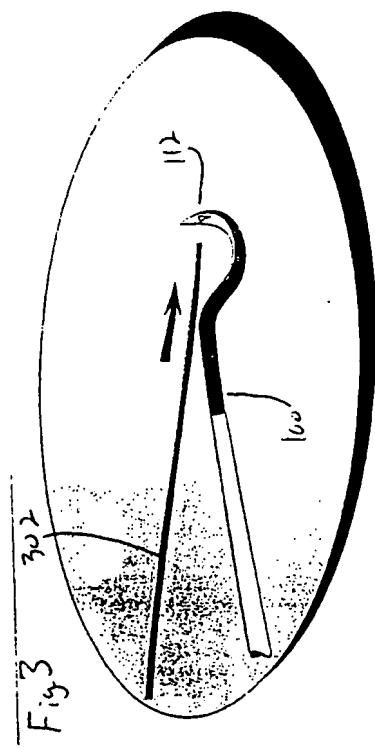
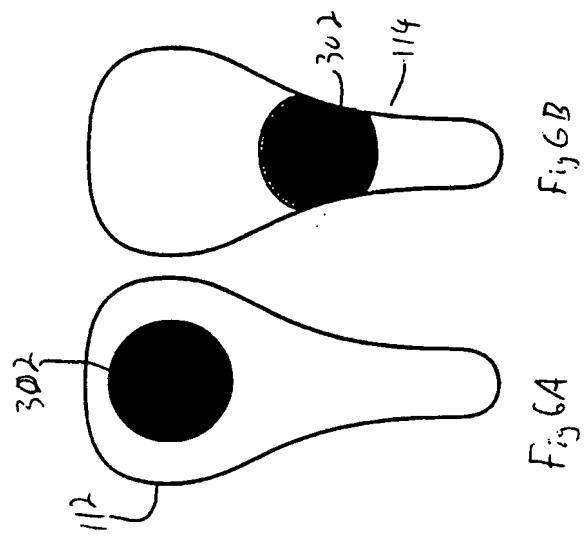
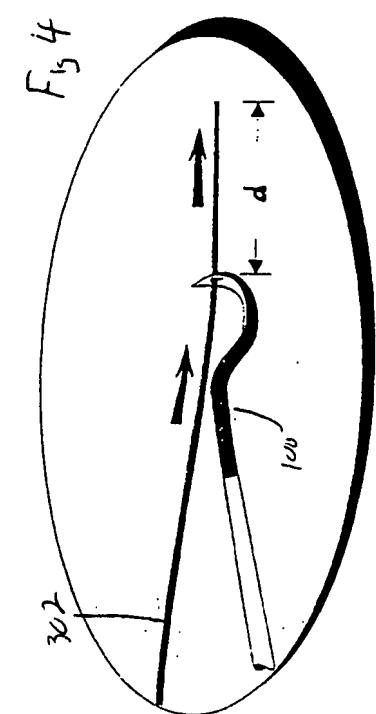


Fig 8

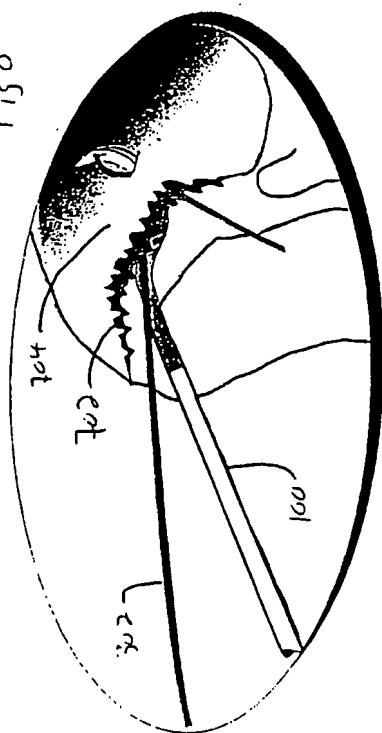


Fig 10

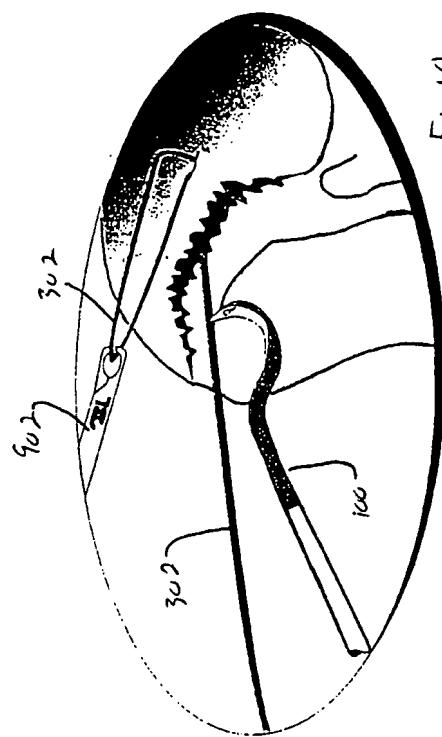


Fig 7

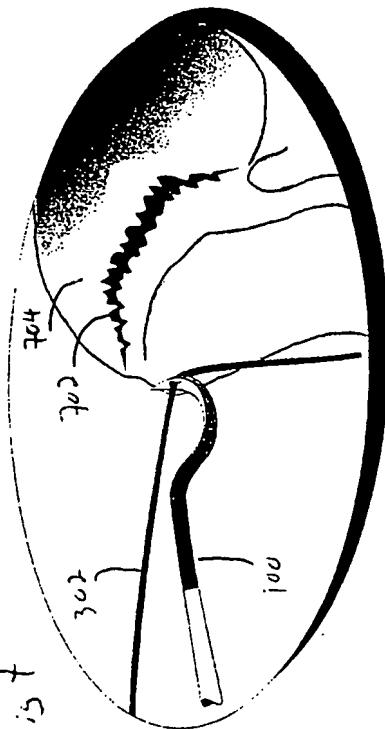
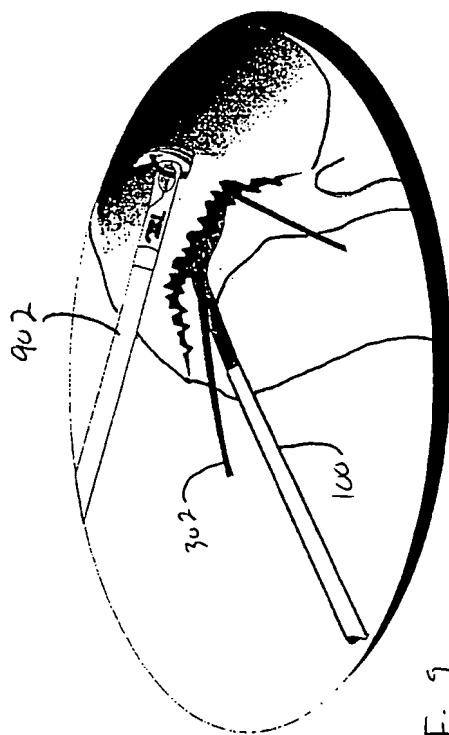


Fig 9



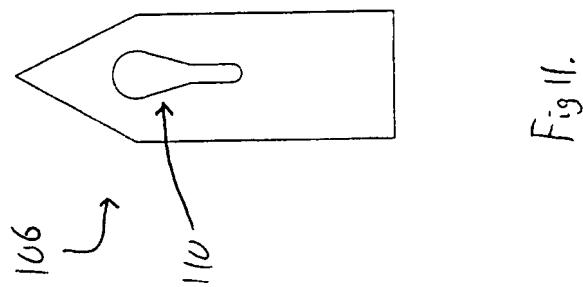
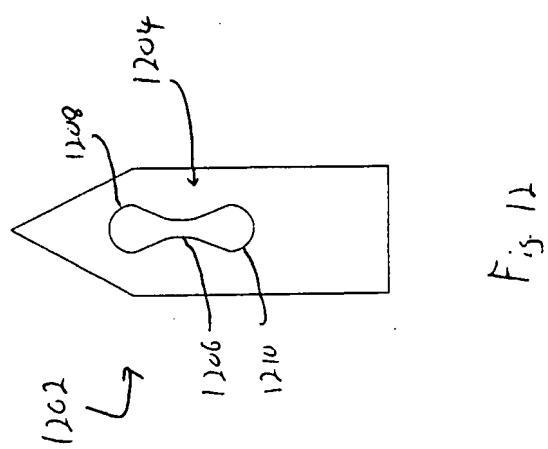
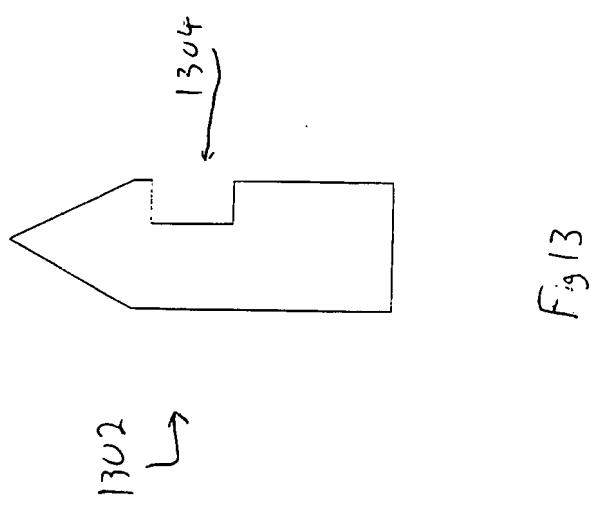


Fig 11.





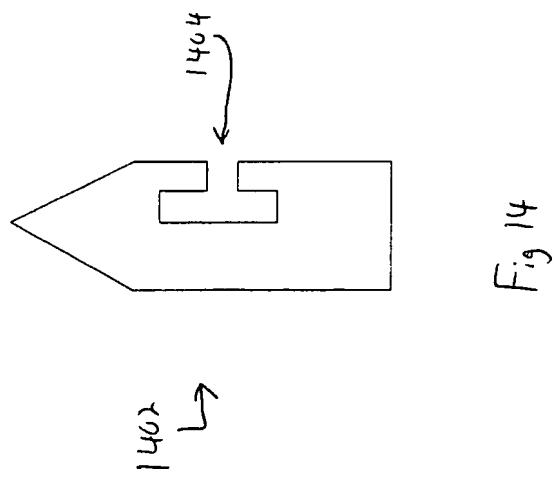
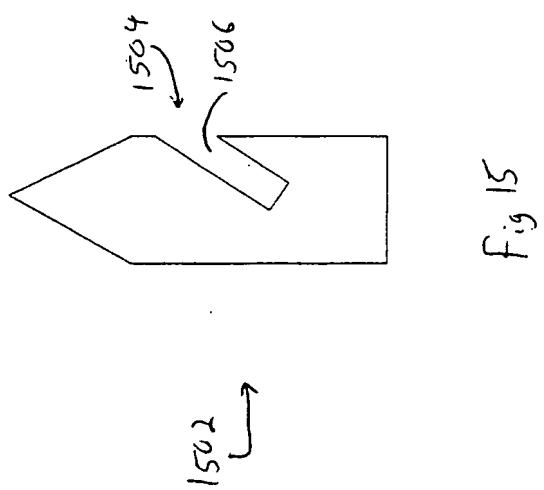


Fig 14



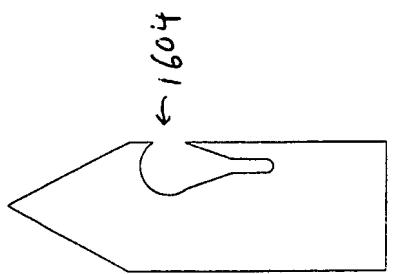


Fig 16

1602

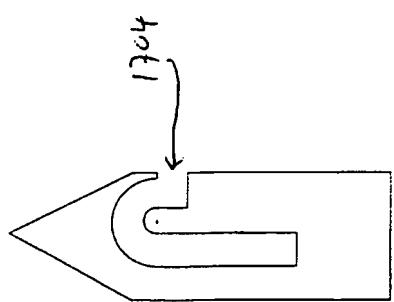
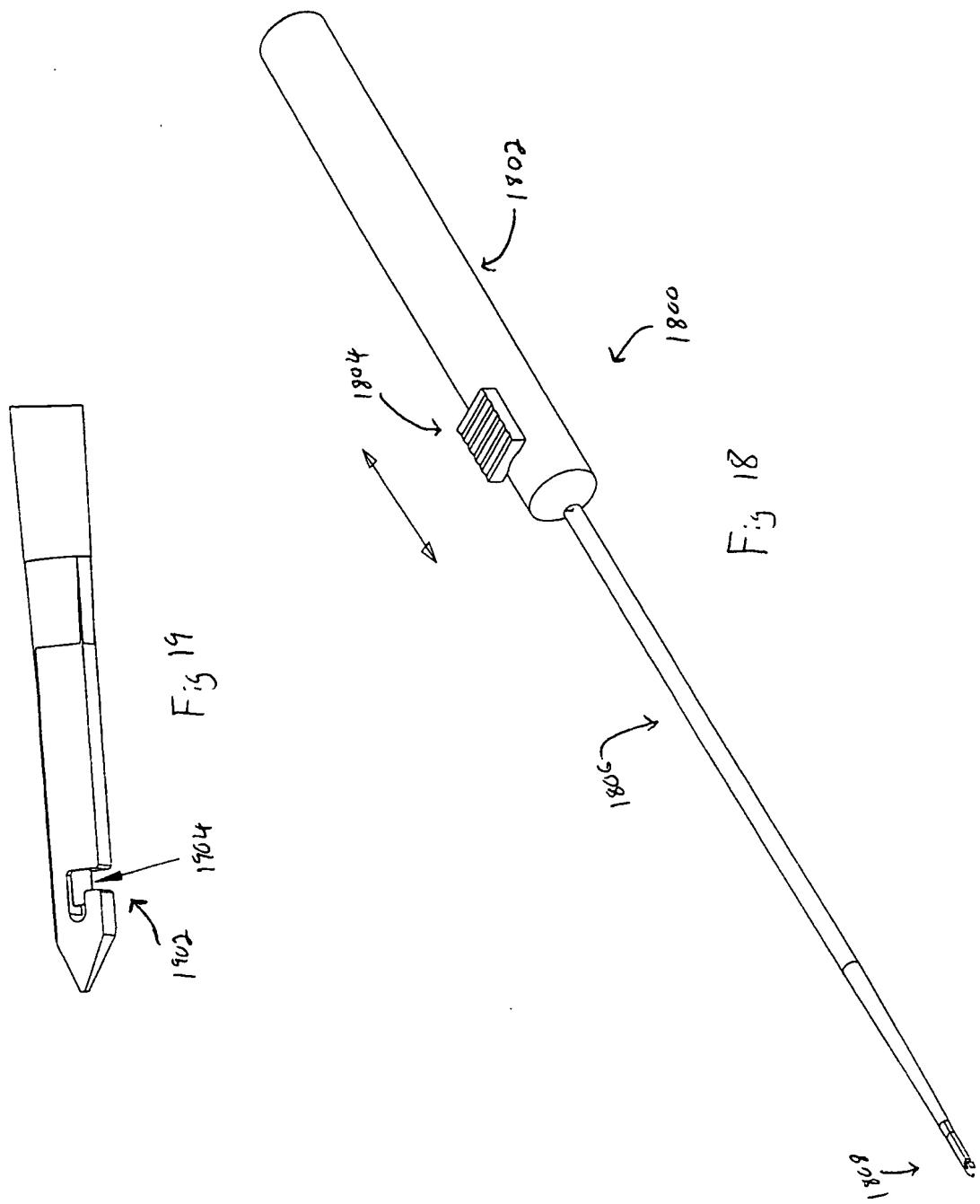


Fig 17

1702



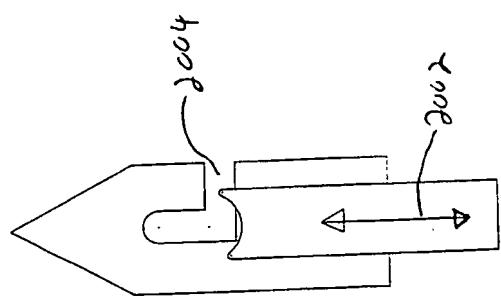
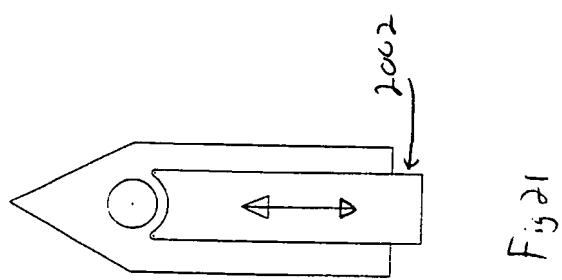
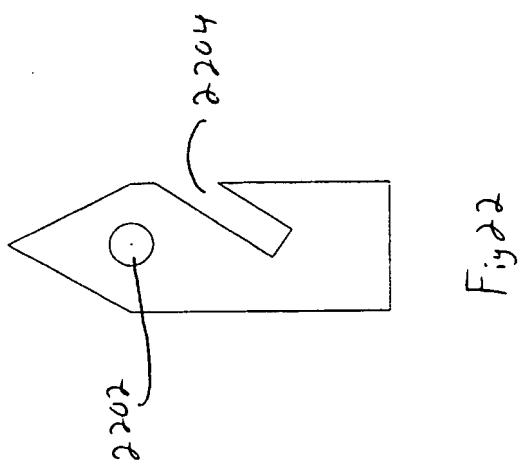
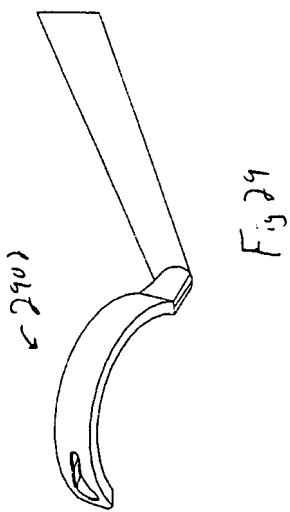
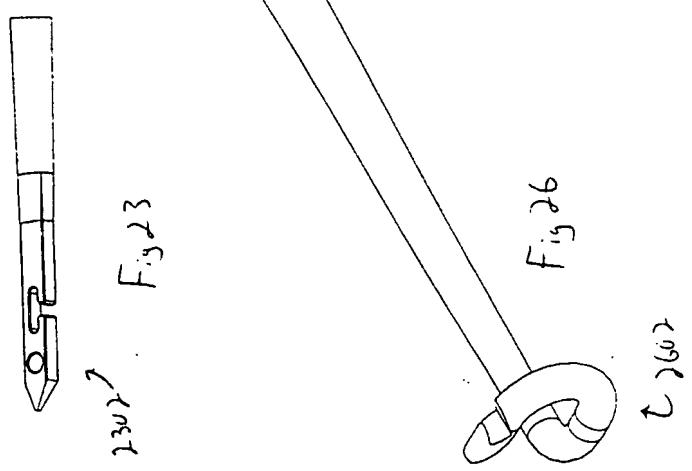
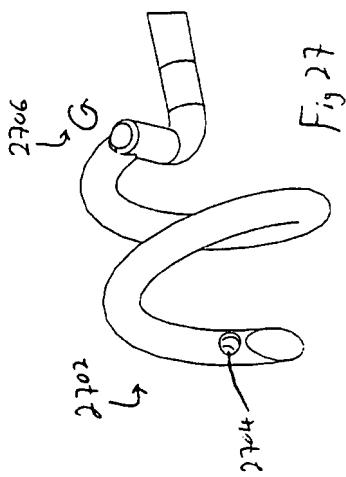
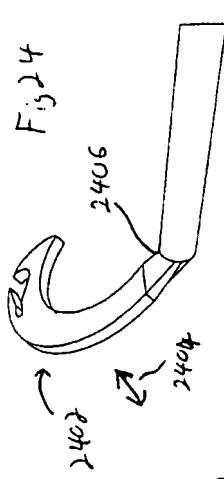
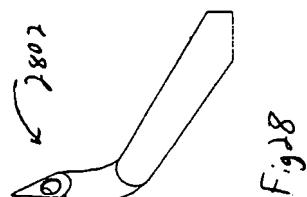
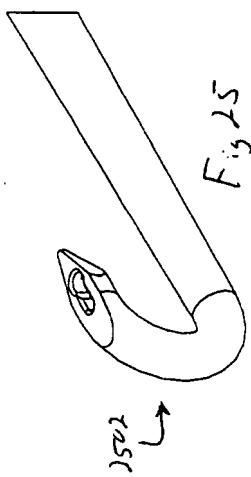
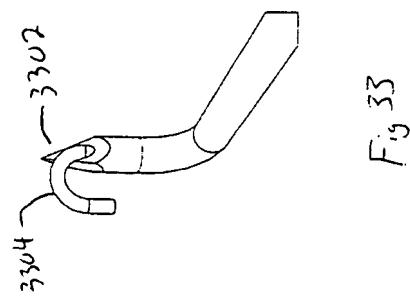
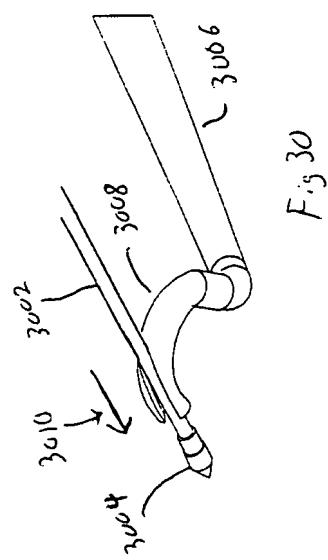
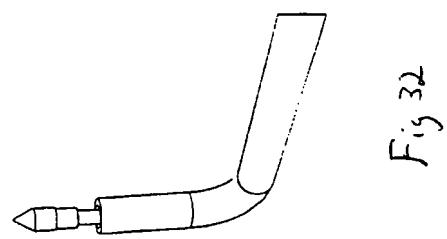
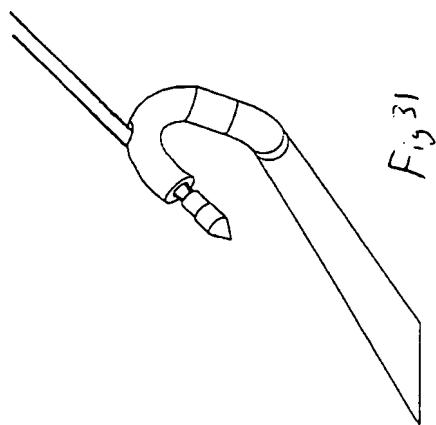


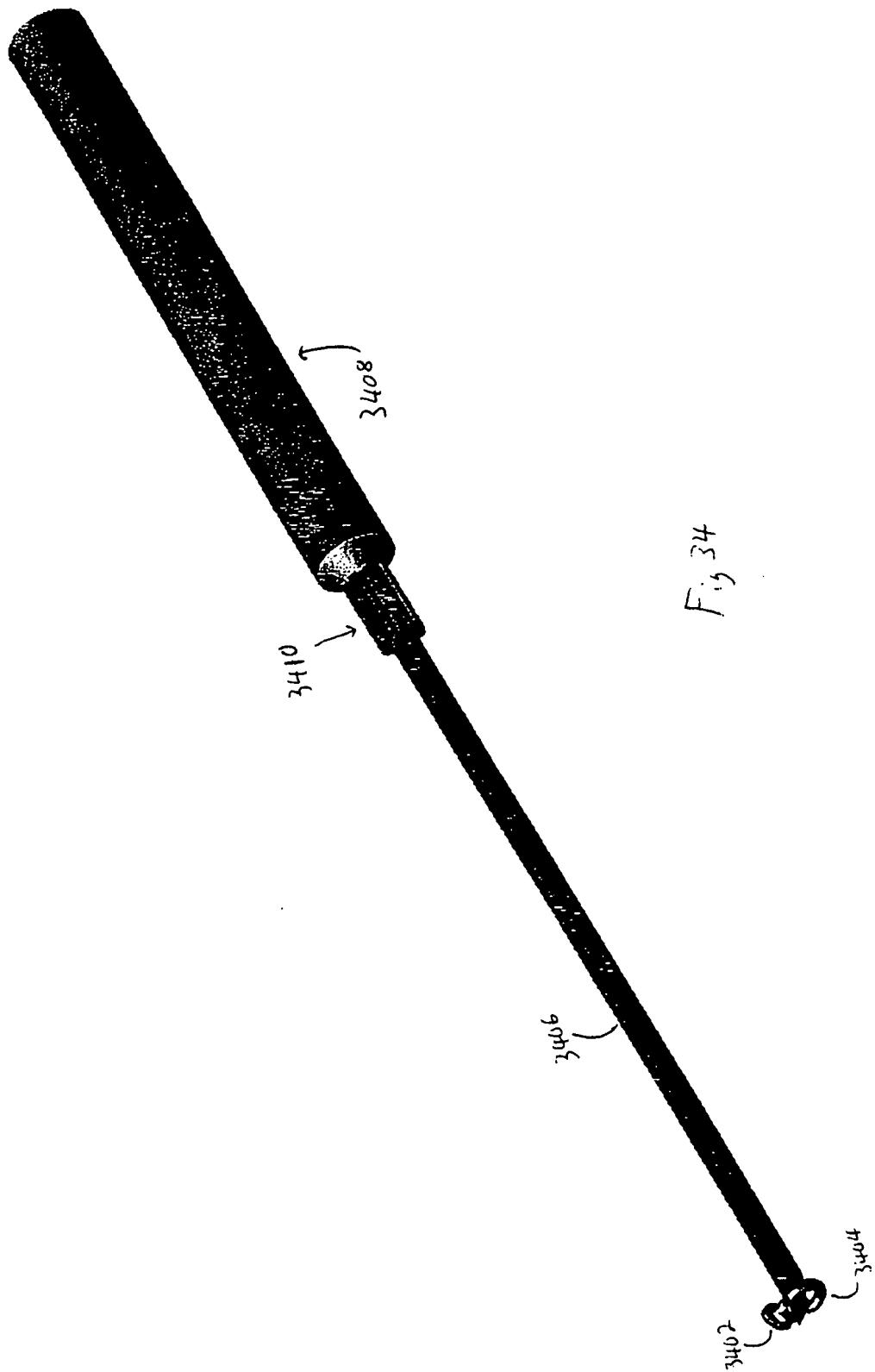
Fig 20











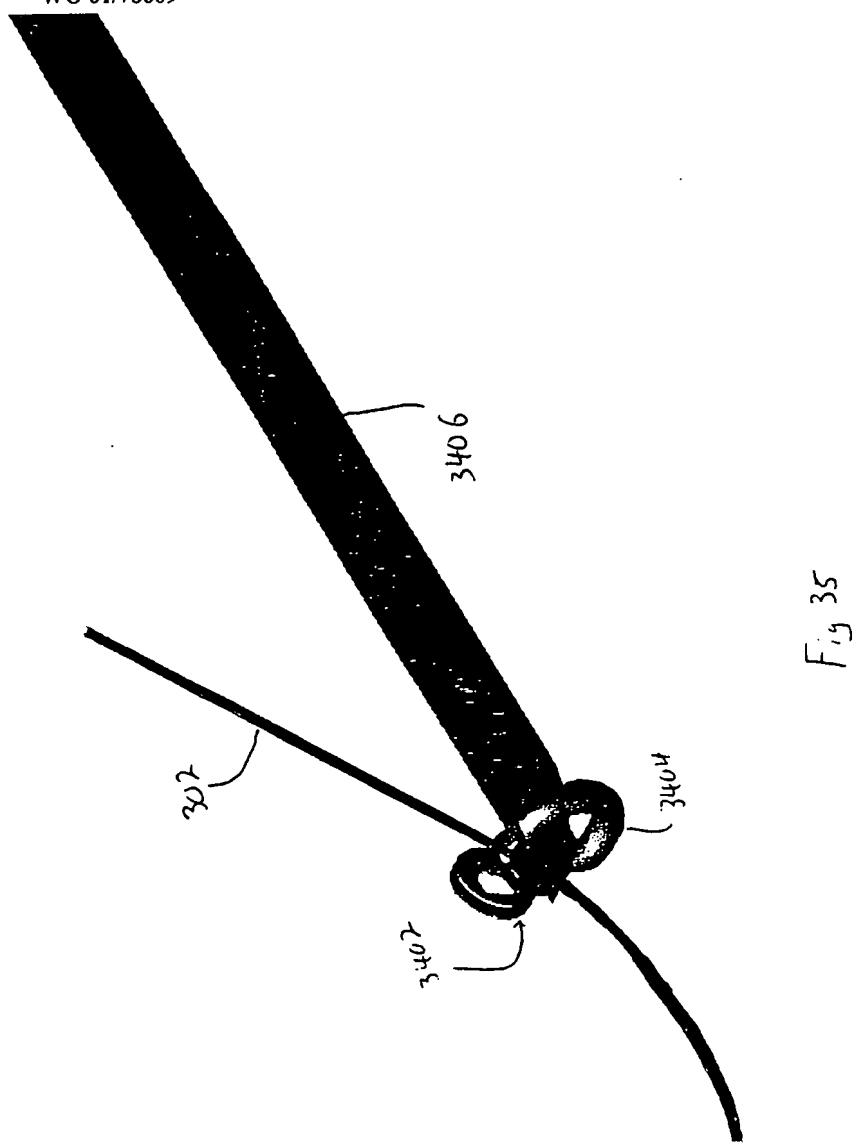
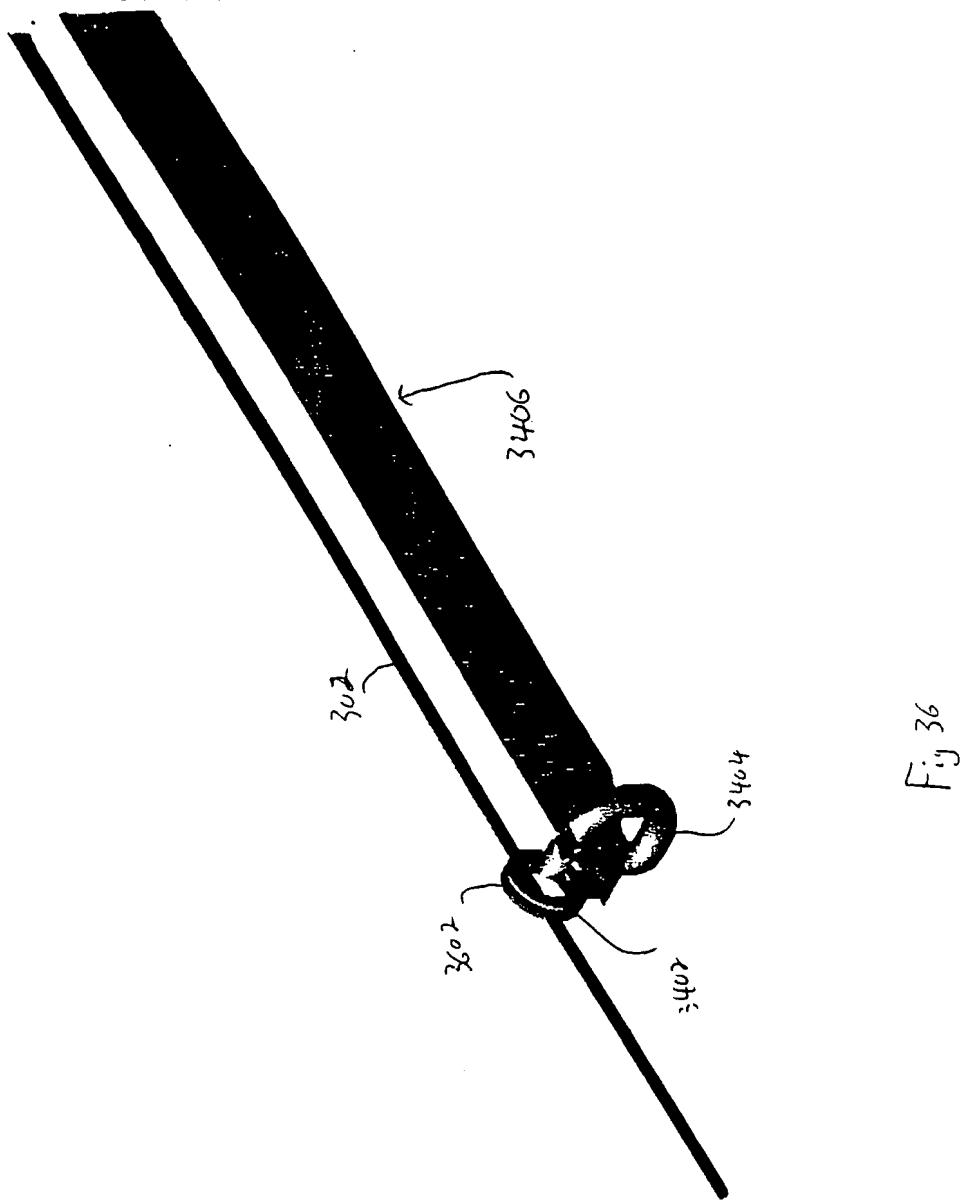


Fig 35

 $F_{ij} 36$

## Suture Passage and Pickup

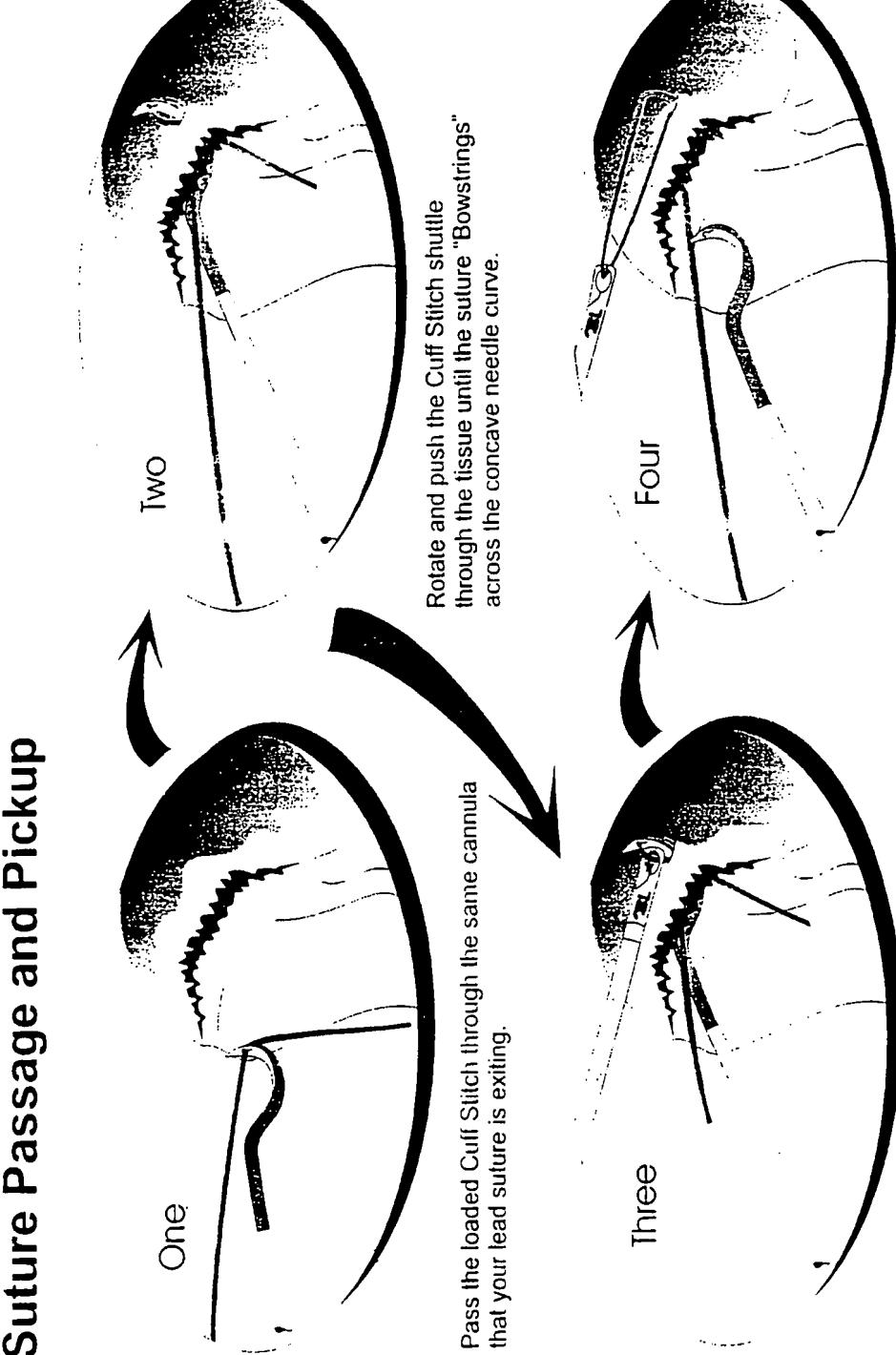


EXHIBIT B

Stitching device with support ring and suture slot (Plate B)



EXHIBIT C

Stitching device with support ring and suture slot (Plate A)

